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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,016	07/06/2005	Amar Lulla	PAC/20632 US (4137-04700)	4912
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CONLEY ROSE, P.C. 5601 GRANITE PARKWAY, SUITE 750 PLANO, TX 75024			BROOKS, KRISTIE LATRICE	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/518,016	Applicant(s) LULLA ET AL.	
	Examiner KRISTIE L. BROOKS	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,6-22,25-30,35-38,44,45 and 53-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,6-22,25-30,35-38,44,45 and 53-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/23/09;8/7/09</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application

1. Claims 1, 2, 4, 6-22, 25-30, 35-38, 44-45 and 53-56 are pending. Claims 53-56 are new.
2. Receipt and consideration of Applicants remarks/arguments submitted on July 23, 2009 is acknowledged.
3. Rejections not reiterated from the previous Office Action are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 1-2, 4, 7-21, 30, 35-38, 44-45, and 53-56 are rejected under U.S.C. 103(a) as being unpatentable over Cramer (EP 0780127).

Applicant claims a pharmaceutical formulation which comprises azelastine, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof and fluticasone, or a pharmaceutically acceptable ester thereof, wherein fluticasone or a pharmaceutically acceptable ester thereof in an amount from about 50micrograms/ml to about 5mg/ml of the formulation.

Determination of the scope and content of the prior art (MPEP 2141.01)

Cramer teaches a nasal spray composition comprising about 0.001 to about 0.2% concentration of a glucocorticosteroid (i.e. beclomethasone, flunisolide, triamcinolone, fluticasone, mometasone, bedusonide and pharmaceutically acceptable salts), 0.01 to about 4% concentration of an antihistamine (i.e. azelastine or pharmaceutically acceptable salt thereof, and an intranasal carrier (see the abstract and page 2 lines 36-45). The composition may contain isotonic agents such as citric acid, boric acid, propylene glycol, etc., thickening agents such as xanthan gum, microcrystalline cellulose, carboxymethyl cellulose, hydroxypropyl cellulose, etc., humectants such as sorbitol, propylene glycol, polyethylene glycol, etc. and preservatives such as

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benzyl alcohol, phenylethyl alcohol, and quaternary ammoniums such as benzalkonium chloride (see page 4 lines 50-58 and page 5 lines 1-22). The composition may contain surfactants such as Polysorbate 80, Octoxynol, etc. (see page 5 lines 11-16). The pH of the composition is from about 4.5 to about 9 (see page 2 lines 57-58). The composition may be formulated into a nasal solution (for use as drops or a spray), a nasal suspension, ointment, or gel (see page 3 lines 43-47). Typically the dosage units may be prepared to deliver 0.5mcg to about 100mcg of the glucocorticoid and 5mcg to about 1000mcg of the antihistamine spray (see page 3 lines 58 and page 4 lines 1-2).

Example III discloses an intranasal pharmaceutical composition prepared by combining the following components utilizing conventional mixing techniques, shown below:

Component	Wgt %
triamcinolone acetonide	0.050
azelastine HCl	0.070
polysorbate 80	0.050
glycerin	2.000
hydroxypropyl methyl cellulose	1.000
sodium chloride	0.500
ethylenediamine tetraacetic acid	0.050
benzalkonium chloride	0.020
distilled water	q.s. to vol.

(see page 6, Example III).

Ascertainment of the difference between the prior art and the claims (MPEP**2141.02)**

Cramer does not exemplify a composition comprising azelastine and fluticasone.

**Finding of prima facie obviousness Rational and Motivation (MPEP
2142-2143)**

However, one of ordinary skill in the art would have been motivated to make a composition comprising azelastine and fluticasone because Cramer suggests that the combination of a glucocorticoid (i.e. fluticasone) and an antihistamine (i.e. azelastine) provide improved relief of symptoms associated with seasonal or perennial allergic rhinoconjunctivitis.

Thus, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make a composition comprising azelastine and fluticasone for the purpose of providing intranasal compositions with improved effectiveness in the treatment of seasonal or perennial allergic rhinoconjunctivitis.

Although Cramer does not specifically teach the instantly claimed ester (or salt) forms of fluticasone (i.e. fluticasone valerate or fluticasone propionate), Cramer suggest that fluticasone can be present in a pharmaceutically acceptable salt form. It would have been obvious to one of ordinary skill in the art to utilize fluticasone in any pharmaceutically acceptable salt form that would be therapeutically beneficial to fluticasone. Further, it is known in the art that pharmaceutically acceptable salt forms can include hydrochloride, propionate, valerate salt, etc. (as evidenced by Link et al. US 6,583,180, see column 183 lines 38-67).

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Therefore, the claimed invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made because the prior art is fairly suggestive of the claimed invention.

7. Claims 22 and 26-27 are rejected under U.S.C. 103(a) as being unpatentable over Cramer (EP 0780127) in view of Modi (US 6,294,153).

Applicant claims a pharmaceutical formulation which comprises azelastine, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof and fluticasone, or a pharmaceutically acceptable ester thereof, wherein fluticasone or a pharmaceutically acceptable ester thereof in an amount from about 50micrograms/ml to about 5mg/ml of the formulation.

Determination of the scope and content of the prior art (MPEP 2141.01)

Cramer teaches a nasal spray composition comprising about 0.001 to about 0.2% concentration of a glucocorticosteroid (i.e. beclomethasone, flunisolide, triamcinolone, fluticasone, mometasone, bedusonide and pharmaceutically acceptable salts), 0.01 to about 4% concentration of an antihistamine (i.e. azelastine or pharmaceutically acceptable salt thereof, and an intranasal carrier (see the abstract and page 2 lines 36-45). The composition may contain isotonic agents such as citric acid, boric acid, propylene glycol, etc., thickening agents such as xanthan gum, microcrystalline cellulose,

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carboxymethyl cellulose, hydroxypropyl cellulose, etc., humectants such as sorbitol, propylene glycol, polyethylene glycol, etc. and preservatives such as benzyl alcohol, phenylethyl alcohol, and quaternary ammoniums such as benzalkonium chloride (see page 4 lines 50-58 and page 5 lines 1-22). The composition may contain surfactants such as Polysorbate 80, Octoxynol, etc. (see page 5 lines 11-16). The pH of the composition is from about 4.5 to about 9 (see page 2 lines 57-58). The composition may be formulated into a nasal solution (for use as drops or a spray), a nasal suspension, ointment, or gel (see page 3 lines 43-47). Typically the dosage units may be prepared to deliver 0.5mcg to about 100mcg of the glucocorticoid and 5mcg to about 1000mcg of the antihistamine spray (see page 3 lines 58 and page 4 lines 1-2).

Example III discloses an intranasal pharmaceutical composition prepared by combining the following components utilizing conventional mixing techniques, shown below:

Component	Wgt %
triamcinolone acetonide	0.050
azelastine HCl	0.070
polysorbate 80	0.050
glycerin	2.000
hydroxypropyl methyl cellulose	1.000
sodium chloride	0.900
ethylenediamine tetraacetic acid	0.050
benzalkonium chloride	0.020
distilled water	q.s. to vol.

(see page 6, Example III).

Ascertainment of the difference between the prior art and the claims (MPEP

2141.02)

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Cramer does not exemplify a nasal composition further comprising a propellant. This deficiency is cured by the teachings of Modi.

Modi teaches aerosol formulations for nasal delivery comprising pharmaceutical agents (i.e. anti-inflammatories, steroids, etc.), water, excipients and a propellant (see the abstract and column 3 lines 30-40). Improved penetration and absorption of the formulations can be achieved by mixing the formulation with propellants such as tetrafluoroethane, etc., especially when delivered through aerosol devices (i.e. MDI). (see column 2 lines 5-24).

**Finding of prima facie obviousness Rational and Motivation (MPEP
2142-2143)**

One of ordinary skill in the art would have been motivated to make a composition further comprising a propellant because Modi suggests that adding propellants to nasal formulations can increase penetration and absorption in the nasal cavity.

Thus, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make a composition further comprising a propellant for the purpose of increasing penetration of active formulations into the nasal cavity.

Therefore, the claimed invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made because the prior art is fairly suggestive of the claimed invention.

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8. Claims 1-2 and 6 are rejected under U.S.C. 103(a) as being unpatentable over Cramer (EP 0780127) in view of Fassberg et al. (US 6,416,743).

Applicant claims a pharmaceutical formulation which comprises azelastine, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof and fluticasone, or a pharmaceutically acceptable ester thereof, wherein fluticasone or a pharmaceutically acceptable ester thereof in an amount from about 50micrograms/ml to about 5mg/ml of the formulation.

Determination of the scope and content of the prior art (MPEP 2141.01)

Cramer teaches a nasal spray composition comprising about 0.001 to about 0.2% concentration of a glucocorticosteroid (i.e. beclomethasone, flunisolide, triamcinolone, fluticasone, mometasone, bedusonide and pharmaceutically acceptable salts), 0.01 to about 4% concentration of an antihistamine (i.e. azelastine or pharmaceutically acceptable salt thereof, and an intranasal carrier (see the abstract and page 2 lines 36-45). The composition may contain isotonic agents such as citric acid, boric acid, propylene glycol, etc., thickening agents such as xanthan gum, microcrystalline cellulose, carboxymethyl cellulose, hydroxypropyl cellulose, etc., humectants such as sorbitol, propylene glycol, polyethylene glycol, etc. and preservatives such as benzyl alcohol, phenylethyl alcohol, and quaternary ammoniums such as benzalkonium chloride (see page 4 lines 50-58 and page 5 lines 1-22). The pH of

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the composition is from about 4.5 to about 9 (see page 2 lines 57-58). The composition may be formulated into a nasal solution (for use as drops or a spray), a nasal suspension, ointment, or gel (see page 3 lines 43-47). Typically the dosage units may be prepared to deliver 0.5mcg to about 100mcg of the glucocorticoid and 5mcg to about 1000mcg of the antihistamine spray (see page 3 lines 58 and page 4 lines 1-2).

Example III discloses an intranasal pharmaceutical composition prepared by combining the following components utilizing conventional mixing techniques, shown below:

Component	Wgt %
triamcinolone acetonide	0.050
azelastine HCl	0.070
polyorbate 80	0.050
glycerin	2.000
hydroxypropyl methyl cellulose	1.000
sodium chloride	0.500
ethylenediamine tetraacetic acid	0.050
benzalkonium chloride	0.020
distilled water	q.s. to vol.

(see page 6, Example III).

Ascertainment of the difference between the prior art and the claims (MPEP

2141.02)

Cramer et al. do not teach the instantly claimed formulation comprising azelastine and fluticasone with a particle size of less than 10 μ m. This deficiency is cured by the teachings of Fassberg et al.

Fassberg et al. teach aerosol formulations for nasal administration comprising 1,1,1,2 tetrafluoroethane and a medicament (see the abstract and column 3 lines 2-7). Examples of the medicaments include antihistamines and

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steroids (see column 5 lines 61-66). The particle size of the active compound ranges from 0.1-25 μ m (see column 6 lines 11-15). The formulation may optionally contain an excipient or surfactant (see the abstract).

Finding of prima facie obviousness Rational and Motivation

(MPEP 2142-2143)

One of ordinary skill in the art would have been motivated to make a composition comprising azelastine and fluticasone with a particle size of less than 10 μ m because Fassberg et al. nasal compositions comprising antihistamines (e.g. azelastine) or steroids (e.g. fluticasone) can be prepared with a particle size ranging from 0.1-25 μ m, which overlaps with the instantly claimed particle size of less than 10 μ m.

Thus, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make a composition with the instantly claimed particle size range because it is an obvious variation of particle sizes that can be used in the preparation of nasal formulations.

Therefore, the claimed invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made because the prior art is fairly suggestive of the claimed invention.

9. Claims 1, 25, 28-29 are rejected under U.S.C. 103(a) as being unpatentable over Cramer (EP 0780127) in view of Alfonso et al. (US 6,017,963).

Applicant claims a pharmaceutical formulation which comprises azelastine, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof and fluticasone, or a pharmaceutically acceptable ester thereof, wherein fluticasone or a pharmaceutically acceptable ester thereof in an amount from about 50micrograms/ml to about 5mg/ml of the formulation.

Determination of the scope and content of the prior art (MPEP 2141.01)

Cramer teaches a nasal spray composition comprising about 0.001 to about 0.2% concentration of a glucocorticosteroid (i.e. beclomethasone, flunisolide, triamcinolone, fluticasone, mometasone, bedusonide and pharmaceutically acceptable salts), 0.01 to about 4% concentration of an antihistamine (i.e. azelastine or pharmaceutically acceptable salt thereof, and an intranasal carrier (see the abstract and page 2 lines 36-45). The composition may contain isotonic agents such as citric acid, boric acid, propylene glycol, etc., thickening agents such as xanthan gum, microcrystalline cellulose, carboxymethyl cellulose, hydroxypropyl cellulose, etc., humectants such as sorbitol, propylene glycol, polyethylene glycol, etc. and preservatives such as benzyl alcohol, phenylethyl alcohol, and quaternary ammoniums such as benzalkonium chloride (see page 4 lines 50-58 and page 5 lines 1-22). The pH of the composition is from about 4.5 to about 9 (see page 2 lines 57-58). The composition may be formulated into a nasal solution (for use as drops or a spray), a nasal suspension, ointment, or gel (see page 3 lines 43-47). Typically

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the dosage units may be prepared to deliver 0.5mcg to about 100mcg of the glucocorticoid and 5mcg to about 1000mcg of the antihistamine spray (see page 3 lines 58 and page 4 lines 1-2).

Example III discloses an intranasal pharmaceutical composition prepared by combining the following components utilizing conventional mixing techniques, shown below:

Component	Wgt %
triamcinolone acetonide	0.050
azelastine HCl	0.070
polyorbate 80	0.080
glycerin	2.000
hydroxypropyl methyl cellulose	1.000
sodium chloride	0.900
ethylenediamine tetraacetic acid	0.050
benzalkonium chloride	0.020
distilled water	q.s. to vol.

(see page 6, Example III).

**Ascertainment of the difference between the prior art and the claims (MPEP
2141.02)**

Cramer does not teach the instant formulation in the form of an insufflation powder. This deficiency is cured by the teachings of Alfonso et al.

Alfonso et al. teaches intranasal and/or inhalation administration of pharmaceutical agents (see the abstract). The dosage form suitable for intranasal and/or inhalation administration can be in the form of a liquid solution suspension, insufflation powder, etc. for administration as a nasal spray, drop or inhaled fine particles (i.e. insufflation) (see column 3 lines 1-65, column 5 lines 36-45, and column 7 lines 1-26).

**Finding of prima facie obviousness Rational and Motivation (MPEP
2142-2143)**

One of ordinary skill in the art would have been motivated to make the instant composition in the form of an insufflation powder because Alfonso et al. suggest the nasal compositions in the form of a spray, droplet, insufflation powder, etc.

Thus, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make the instant composition in the form of an insufflation powder because it is an obvious variation of ways to administer a nasal composition, as suggested Alfonso et al.

Therefore, the claimed invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made because the prior art is fairly suggestive of the claimed invention.

Response to Arguments

Applicant's arguments filed August 7, 2009 have been fully considered but they are not persuasive.

Applicant argues that Cramer is not fairly suggestive of the instantly claimed combination and that the particular combination instantly claimed is not explicitly mentioned.

This argument is not persuasive. Cramer specifically teaches a nasal spray comprising the combination of a glucocorticoid (i.e. fluticasone) and an antihistamine (i.e. azelastine). There are a limited number of glucocorticoids (six)

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and antihistamines (three) recited. It is well within the means for one of ordinary skill in the art to try the instant combination as there are a small number of actives to choose from. Furthermore, disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971).

Next, Applicant argues that the combination of azelastine and fluticasone display unexpected beneficial results. Applicant provides a 1.132 declaration, submitted on July 23, 2009, as evidence of the superior combination.

1.132 Declaration

The declaration provided by Applicant provides a table (Table I) that discloses five compositions, i.e. budesonide alone, azelastine alone, azelastine and budesonide, fluticasone alone, and azelastine and fluticasone. The table also lists the ingredients or excipients added to each composition.

Table II compares the stability of each composition by disclosing the total impurity level of the composition, at the beginning of testing, after one month, and after three months of storage. The impurity level for the composition comprising azelastine and fluticasone appears to remain low and consistently stable throughout the testing period when compared to the composition comprising azelastine and budesonide.

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However, this data is not persuasive. First, Applicant has not described what testing method was used, what assay was utilized, and how the impurity level was calculated.

Second, Applicant has not described what the impurity is. It is unclear if the impurity arises from the active, excipients, formulations, etc.

Third, Applicant did not test against the closest prior art examples, described in Cramer (see Example 3). Example 3 in Cramer discloses a composition comprising azelastine and triamcinolone.

Last, it should be noted in Table I, that the instant composition comprising azelastine and fluticasone contains phenylethyl alcohol (a preservative/antibacterial), whereas the composition comprising azelastine and budesonide does not. It is well known in the art that a preservative is added to composition to prevent decomposition of a substance and to destroy or inhibit multiplication of microorganisms, which also causes decomposition (as evidenced by Dorland's Medical Dictionary, Mosby's Medical Dictionary, and American Heritage Medical Dictionary, see 892 form). It is further known that a preservative increases the shelf life of compositions (as evidenced by Cramer page 5 lines 16-18).

Applicant is predicated its unexpected results of the instant formulation by measuring the level of impurity in the formulations when compared compositions with similar actives. However, an extremely critical element is missing from the comparative composition. It is neither unexpected nor surprising that a composition comprising an additional preservative would be capable of keeping

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impurity levels lower and increasing shelf life when compared to a composition that does not contain the preservative or a lesser amount of preservative.

Applicant also provided a compilation of statements from 6 medical practitioners that attest to the various advantages and superior results associated with the use of the instant invention. Applicant further argues that there is a long felt need for an improved nasal formulation and that the instant composition, known as DUONASE, is a commercial success.

However, given the deficiencies in the data provided by Applicant, one of ordinary skill in the art cannot accurately ascertain whether any unexpected results have occurred.

Therefore, Applicant's arguments and evidence of nonobviousness are not persuasive.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory

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period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISTIE L. BROOKS whose telephone number is (571)272-9072. The examiner can normally be reached on M-F 8:30am-6:00pm Est..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KB

/Mina Haghighatian/
Primary Examiner, Art Unit 1616